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Percutaneous lead extraction and venous recanalisation using spectranetics tight rail: A single centre experience

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ABSTRACT

Aims: Despite advances in lead extraction tools, percutaneous lead extraction remains a complex procedure associated with significant morbidity and mortality. Moreover, no standards or directives exist to guide physicians in the choice of their extraction tool or approach and all operators tend to have their own preferred method. The reporting of outcomes with existing and newly emerging extraction technology is therefore encouraged.

Methods and results: Four lead extraction procedures using the new spectranetics tight rail rotating dilator sheath are described here. All patients (n = 3) had chronically implanted leads (mean duration = 11.7 years) and the pre-procedure venogram showed occluded left subclavian and brachiocephalic veins with extensive collateralisation. All leads were extracted successfully using this newly designed rotating dilator sheath and vascular access was also retained by venous recanalisation using this kit. One patient required a second extraction procedure at four weeks due to diaphragmatic twitch without macroscopic coronary sinus (CS) lead displacement. This was replaced with a transseptal LV lead. There were no other procedure related complications and all patients remained well with good lead parameters at three months follow-up.

Conclusion: The use of this new tight rail extraction tool appears safe and effective in chronically implanted leads. Moreover, it helps to preserve the vascular access by recanalisation of long tortuous occlusions. Its use across various centres and larger number of patients will be required to confirm our results.

1. Introduction

The rapidly increasing number of cardiac implantable electronic devices (CIED) over the past two decades [1] has lead to a growing trend of percutaneous lead extraction procedures. The latter have increased as a result of lead failure, infection, lead—lead interactions, venous stenosis or thrombosis, chronic pain at the device or lead insertion site, life-threatening arrhythmias secondary to retained leads and the need to upgrade to a new technology [2].

The challenges and risks of transvenous lead extraction largely stem from the individual's foreign body response to the CIED. This starts with thrombus development along the lead at the time of implantation, progressing thereafter to fibrosis of the thrombus with near complete encapsulation of the leads with a fibrin sheath within 45 days of the implant [3,4]. Multiple areas of fibrosis and calcification are found in most patients with the commonest adhesion sites being the venous entry site, superior vena cava and the electrode-endomyocardial interface [5]. These increase the challenges and risks associated with lead extraction.

Lead extraction has evolved exponentially over the last decade. While manual traction might suffice for a recently implanted lead (<1 yr old), chronically implanted leads require more advanced endovascular extraction tools including simple traction (non-locking stylets, fixation screw retraction clips), non-powered extraction tools (locking stylets, mechanical dilator sheaths) and powered extraction tools (laser sheaths, electrosurgical dissection sheaths, rotating threaded tip sheaths). Despite the advances in lead extraction tools, this intervention remains a complex procedure and is associated with significant morbidity and mortality despite accounting for operator skill and experience [6,7].

To date, several studies have described the efficacy of the vast number of extraction tools available. However, no standards or directives exist to guide physicians in the choice of their extraction tool or approach and all operators tend to have their own preferred method. The HRS 2009 Expert Consensus on transvenous lead extraction provides several recommendations to help the specialty of lead extraction evolve. One of these includes the reporting of outcomes with existing and newly emerging extraction technology.

In this case series of four procedures in three patients, we report our experience with the new Spectranetics Tight Rail extraction tool. Its efficacy in extraction of chronically implanted leads and recanalisation of long occlusions was investigated.

2. Case histories

2.1. Patient 1

53-year-old man with known pulmonary and cardiac sarcoid, who presented with haemodynamically compromising ventricular tachycardia requiring DC cardioversion. He had a permanent pacemaker (PPM) implanted five years ago for symptomatic first-degree heart block. Prior to this admission, he had previously declined the offer of a cardiac resynchronisation therapy defibrillator (CRTD), to which he now consented.

An echocardiogram on this admission confirmed significant left ventricular (LV) impairment and dilatation (LVID 67 mm, LVEF 30%) with global hypokinesia. There was no significant valvular disease or evidence of pulmonary hypertension. Pacemaker interrogation showed high right ventricular (RV) lead impedance as well as threshold and the CXR was suggestive of lead fracture. A venogram done prior to the procedure showed occluded left subclavian and brachiocephalic veins with extensive collateralisation. It was therefore decided to proceed with RV lead extraction, preservation of vascular access and upgrade to a CRTD.

2.2. Patient 2

44-year-old man who was admitted electively for a PPM generator change and new atrial (A) lead. His initial PPM implant was twenty years ago for atrioventricular nodal disease and he had also undergone a generator change ten years ago.

An echocardiogram revealed a structurally normal heart. A routine device check revealed that the generator had reached ERI and the A-lead had failed with a suspected lead fracture. A venogram done prior to the procedure demonstrated occluded left subclavian and brachiocephalic veins with extensive collateralisation. Hence, it was decided to extract the A lead, preserve vascular access and implant a new A lead along with the PPM generator change.

2.3. Patient 3

67-year-old man, elective admission for new LV lead implantation. His medical background included PPM implant for complete heart block post-op aortic valve replacement ten years ago. This was later upgraded to a CRTD due to impaired LV function. During the CRTD upgrade, it was not possible to implant the RV shock lead and LV lead on the left side because of an occlusion from the PPM and so these were placed on the right side and tunneled across to the left to be connected to the generator along with the atrial lead. The patient reported deterioration in his quality of life (largely due to increasing heart failure symptoms) and this coincided with a loss of LV lead capture despite maximal output.

An echocardiogram showed poor LV function with a severe dilatation of the aortic root (5.3 cm) and the ascending aorta (5 cm).

He was therefore admitted for extraction of the existing LV lead and for a new epicardial or transseptal LV lead implant. Venogram prior to the procedure showed an occluded left subclavian vein with extensive collaterals — Fig. 1.

3. Lead extraction kit

All lead extractions in this case series were performed using the recently released endovascular Spectranetics Tight Rail Rotating Dilator Sheath extraction kit. The Spectranetics tight rail is a 'hand powered' mechanical sheath, which consists of a flexible inner shaft, static outer shaft (optional), shielded dilation blade with a bidirectional rotational mechanism and a trigger activation handle.

The flexible inner shaft enables the operator to remain coaxial to the lead while maintaining forward progression through tortuous vasculature and fibrotic/calcified lesions. The inner sheath is attached to a trigger activation handle that rotates the sheath and activates the blade. The dilating blade remains shielded (until activated by the operator) and hence allowing safe counter-traction at the lead's distal tip. The blade has bi-directional mechanism, which rotates 540° with each full trigger activation (270° clockwise and 270° counterclockwise) while extending the blade just 0.5 mm to allow dilatation of fibrosed and calcified lesions. The outer shaft is optional and does not rotate with the blade. This can be used based on clinical scenario and operator preference.
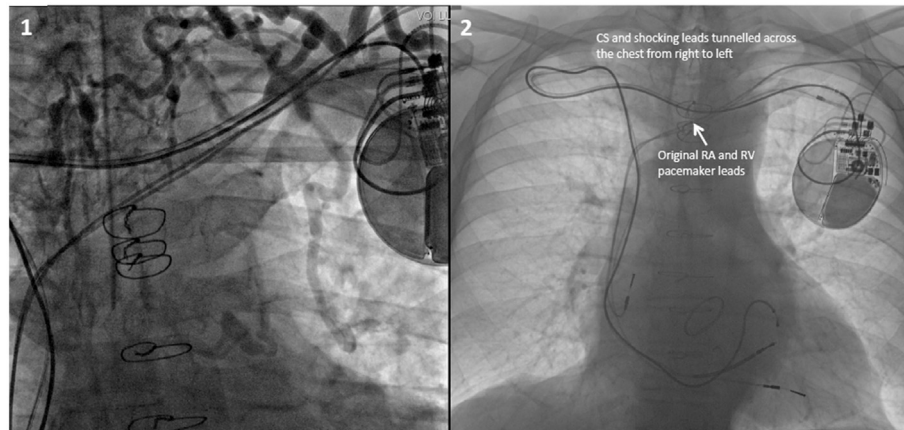
4. Lead extraction procedure

4.1. The technique

The lead extraction procedures were carried out in the cardiac catheterisation laboratory either under a general anaesthetic or under conscious sedation and local anaesthesia with invasive blood pressure and oxygen saturation monitoring. Cardiothoracic surgery team was available on site. Temporary transvenous pacing was established if necessary. For all cases, intravenous antibiotics were administered prior to the procedure and aseptic environment maintained. After skin preparation, the generator pocket was opened and the leads disconnected from the CIED generator and then separated from the scar tissue using blunt dissection and cutting diathermy. All leads were extracted by a superior approach via the implant vein using the tight rail extraction kit described above.

In the first case, the RV lead was freed from the muscle but it was not possible to release the deployed screw of the active fix mechanism as the screw mechanism failed. The RV lead was therefore grabbed with needle eye snare with initial positioning with the help of irrigated F-curve ablation catheter and the snare was fixed on heel of RV lead. Next a 11Fr tight rail system was used which freed the active fix RV lead completely, necessitating release from the needle eye snare and easy extraction from above. Vascular access was retained via the tight rail sheath, however, initially it was not possible to feed the terumo wire down the SVC. A multipurpose catheter was used and contrast injection revealed a false lumen (formed by RV lead) draining into brachiocephalic true lumen via a collateral. The true lumen of the brachiocephalic vein was cannulated via the collateral using a multipurpose catheter. Tight rail was exchanged for long 11 Fr sheath over the wire and an active RV lead delivered to RVA. Also, the CS was cannulated with a multipurpose deflectable catheter with 130° inner and an epicardial CS lead was placed in a posterolateral branch. Good lead parameters observed on both RV and LV leads.

In the second case, initially an 11Fr tight rail kit was used. However, it was not possible to extract the lead due to presence of extensive fibrotic tissue and multiple adhesions. This was therefore

Fig. 1. Pre-procedure venogram and lead position for Case 3. Figure showing pre-procedure venogram with occluded left subclavian and brachiocephalic veins (1) and lead positions prior to extraction (2).

upgraded to a 13 Fr tight rail kit. Subclavian and brachiocephalic occlusions were recanalised using the tight rail and the atrial lead successfully explanted. Vascular access was preserved by passing a long J wire down to IVC via the tight rail sheath, which was then exchanged for a long 11Fr sheath. An active A lead was then implanted next to the RAA and tested with good lead parameters.

The third case was performed under general anaesthesia. Right femoral arterial and venous access was obtained for invasive arterial pressure monitoring and anticipating the potential need for transseptal LV lead placement. After removing the generator from the pocket, the atrial and RV shock and pace-sense leads were freed from the muscle. The atrial lead was extracted using a 13 Fr tight rail. While extracting the A lead, the RV shock coil lead insulation was damaged. It was therefore freed from the left pectoral muscle along-with the LV lead. As both these leads were originally tunneled across from the right, a separate right infraclavicular incision was made and the RV shock coil and LV lead extracted from the right side using a 13Fr tight rail kit. Vascular access was preserved by recanalisation of the veins using a 13Fr tight rail on the left side during the A lead extraction. The tight rail was then exchanged for a long 13Fr and medtronic deflectable sheath. A new active fix, single coil RV lead was delivered to the RV septum and a quadripolar lead to the distal middle cardiac vein. The old RV pace-sense lead was capped and buried. Fig. 2 shows the progression of the tight rail sheath through the occluded left subclavian and brachiocephalic veins and extraction of A lead alongwith recanalisation of the obstructed vasculature.

Unfortunately, the patient developed diaphragmatic twitch
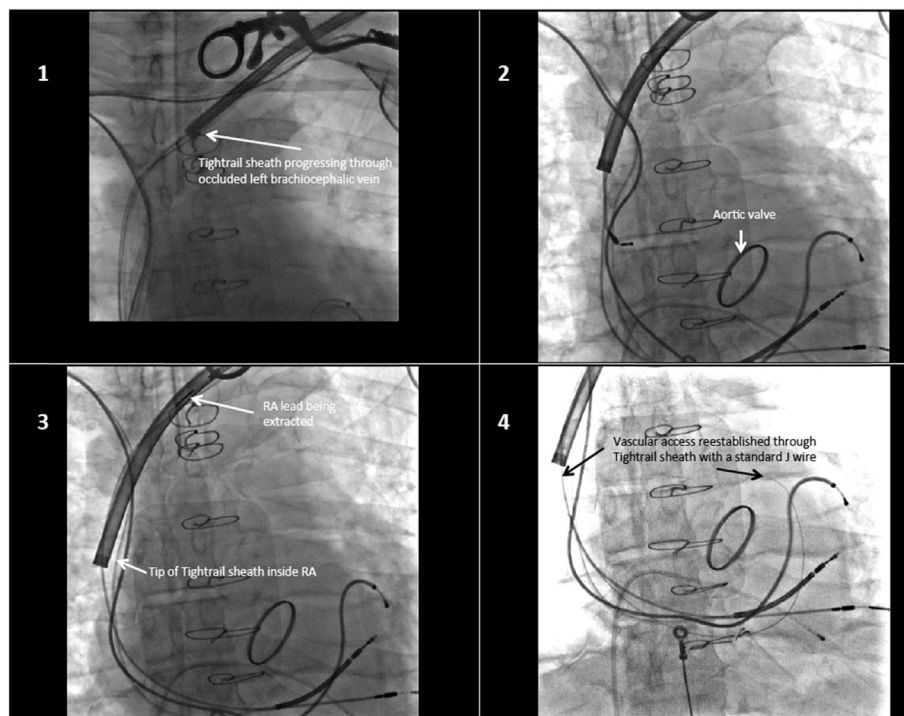
Fig. 2. Tightrail extraction kit progression through vasculature in Case 3 (first procedure). This figure shows the progression of the tight rail sheath through occlusions in the vasculature. Progression through occluded left brachiocephalic vein is shown in (1); the tip of tight rail sheath is in the RA and the A lead has been extracted in (3); vascular access has been re-established in (4).

within four weeks without macroscopic CS lead displacement. The recently implanted middle cardiac vein lead was therefore extracted and a transseptal endocardial LV lead implanted. A venogram at the start of this procedure confirmed brachiocephalic occlusion as before. Not surprisingly, the passive middle cardiac vein lead retracted into the right atrium following locking stylet insertion. Consequently, no traction could be applied to the lead. A 13Ffr tight rail sheath was able to traverse the occluded left brachiocephalic vein, SVC and enter the right atrium without any further retraction of the LV lead. The latter was easily extracted and vascular access reestablished through the tight rail sheath. This was then used to implant a transseptal LV lead. There was no significant change in the position of other leads − Fig. 3.

4.2. Outcomes

All three cases were a clinical success exhibited by complete removal of all targeted leads and lead material from endovascular space with no retained fragments. One patient had a second extraction procedure due to diaphragmatic twitch without macroscopic CS lead displacement. A new transseptal LV lead was implanted at the time of extraction. However, he had had problems with stability of CS lead in the past and it was anticipated that a transseptal LV lead would be required. There were no procedure related major or minor complications and cardiothoracic input was not required. All patients made a good post-procedure recovery and were discharged home within 48hours of the procedure. They remained clinically well with good lead parameters on their three-month follow up.

5. Discussion

The increase in the number of CIED implants in the past decade has been paralleled by an increase in device extraction. Lead extractions are performed in various centres using a variety of extraction tools with a marked reported difference in clinical success rates [8]. In this rapidly evolving field, new extraction tools and techniques are being introduced and require reporting of clinical outcomes to help build a standardised approach to lead extraction.

Here we report the efficacy of a novel mechanical dilator sheath in percutaneous endovascular lead extraction and recanalisation of long occlusions for preservation of vascular access. The bidirectional cutting mechanism of the spectranetics tight rail effectively dilates calcified and fibrosed lesions with the dilating blade being safely shielded until activated. Moreover, the system has enough

flexibility to remain coaxial to the lead and enable steady forward progression through tortuous vasculature safely. Furthermore, little or no traction is required on the locking stylet since the tight rail sheath is very flexible. This allows it to follow the body of the lead around bends such as the left brachiocephalic-SVC junction and through tortuosities minimising the risk of traction-induced conductor coil fracture. Significant traction to the locking stylet is only necessary once the tip of the tight rail sheath is in contact with the endocardium and counter-traction can then be applied permitting a more controlled lead extraction. Since the teeth on the tight rail sheath are concealed, counter-traction can be safely applied without risk of direct trauma to the endocardium.

Since the first report on lead extraction procedures in 1968 this intervention is growing to become a discipline in itself. Despite several available extraction tools, no standardised approach or recommendations for choice of extraction tool or technique exist. With a combination of extraction tools, the success rates of lead extraction can be increased to 96% [9]. However, along-with immediate procedural success, clinical safety and economic aspects have to be considered. Moreover, efficacy and safety optimisation efforts for existing and newly emerging tools and techniques should focus on extraction of long implanted leads.

Our patient cohort comprised a varied group. It exhibited devices with leads in situ for a significant period of time ($\geq$10yrs), particularly prone to calcification and fibrosis, a combination of pacing and defibrillator leads, endocardial and epicardial leads with greater concerns regarding perforation of more tortuous and fragile coronary sinus branches. Also, all three cases had long venous occlusions with extensive tortuous collaterals on venogram. With this novel kit, not only was it possible to extract chronically implanted leads safely but it also enabled preservation of vascular access by recanalisation of long occlusions.

In this diverse patient group, the tight rail system has proved to be clinically safe and effective in experienced hands. Moreover, its relatively lower cost compared to powered tools like lasers makes it a lucrative option for lead extraction. The mechanical nature of this tool might make it more vulnerable to procedural complications in the setting of multiple, severe adhesions. However, more data and reporting of outcomes is required to investigate this.

6. Conclusions

We have demonstrated the use of recently introduced spectranetics tight rail mechanical dilator sheath as an effective first-line method for chronically implanted CIED leads. It has the
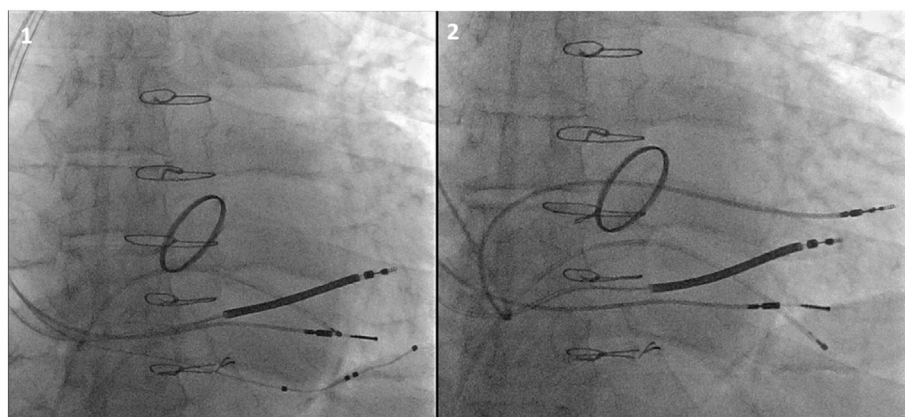
Fig. 3. Pre-procedure lead position with displaced CS lead (1) and transseptal LV lead post extraction of CS lead (2) in Case 3 (second procedure). This figure shows the lead positions in case 3 after the first extraction procedure. The CS lead has retracted (following locking stylet insertion) and is freely moving in the middle cardiac vein (1). This was extracted using the tight rail kit and a transseptal LV lead implanted with no significant change in the position of other leads (2).

added benefit of successful recanalisation of long occlusions. Continued investigation is required to evaluate its efficacy and risks in comparison with other techniques.

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